

## REMARKS

Claims 82-91 and 103-114 are pending. Claims 82, 103, and 105 are amended. Support for the amendments is found throughout the specification as originally filed, and no new matter is added. Reconsideration of the application is respectfully requested.

### 1. 35 U.S.C. §103 Rejections

#### *Rosenman and Rosenwald*

Claims 82-89, 91, 103-111, and 114 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,487,776 to Rosenman et al. (hereinafter “Rosenman”) and U.S. Patent No. 4,678,466 to Rosenwald (hereinafter “Rosenwald”). Applicants respectfully traverse.

Applicants recite, in amended claim 82, a method for treating a patient comprising: (a) providing a delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and a cap member that abuts an incision through which the device is inserted to stabilize the device once implanted, and (b) inserting into a patient ear the device, whereby the device is inserted into the ear through an incision until the cap member abuts the incision, and wherein the cap member remains outside the incision and the body member resides in the patient ear and a therapeutic substance is administered to the patient via the body member.

Rosenman describes a catheter system and drug delivery structure specifically adapted for insertion into the heart. As shown in Fig. 16, Rosenman’s drug delivery structure 12 is implanted within the myocardium so that the proximal tip 38 of the structure 12 is at depth below the endocardial surface 44. Rosenman specifies that this placement is important because it allows the endocardium to heal over the small wound created by implanting the device such that the drug delivery structure will be sealed off from the circulating blood within the heart chamber (See e.g. co. 10 line 62 - col. 11, line 9 and col. 14, line 16- col. 15, line 8). As acknowledged by the Office, Rosenman’s head 56 “abuts the incision from within the tissue” (see page 2 of the Office action).

Thus, Rosenman clearly does not teach or suggest Applicants' method of inserting a device into the ear through an incision until the cap member abuts the incision, and wherein the cap member remains outside the incision and the body member resides in the patient ear and a therapeutic substance is administered to the patient via the body member. Further, there is no teaching or suggestion to modify Rosenman because this would change the principle under which the Rosenman device was designed to operate.

Rosenwald does not remedy these deficiencies. Rosenwald describes a medication delivery vehicle that is inserted within bodily conduits, orifices, vessels and the like (see col. 3, line 48 -line 64) which lead to the particular organ to which medication delivery is sought. In other words, Rosenwald is not inserted through an incision. The Rosenwald vehicle, as shown in Fig. 1, is provided in a truncated conical shape so that body fluids may pass by it once it is implanted (See e.g., col. 3, lines 56-60). Further, Rosenwald does not teach or suggest a cap member of any type that abuts an incision through which the device is inserted and which remains outside the incision for stabilizing the device once it is implanted. Rather, according to Rosenwald, the truncated conical shape of the vehicle assures secure retainment of the vehicle. (See e.g. col. 2, lines 60-64; col. 6, lines 15-20)

Therefore, even if Rosenman and Rosenwald were combined, the present invention would not be obtained. Accordingly, claim 82 is patentable over Rosenman and Rosenwald. Claims 83-89, 91, 103-111, and 114 depend from claim 82 and, thus, also are patentable over Rosenman and Rosenwald.

Applicants recite, in amended claim 103, a method for treating a patient comprising (a) providing a delivery device comprising a therapeutic substance and a coil-shaped body member having at least two deviations from a linear path and a cap member that abuts an incision through which the device is inserted to stabilize the device once implanted, and (b) inserting the device through an incision in a patient ear by twisting or screwing the coil-shaped body member in

through the incision until the cap member abuts the outside of the incision, whereby the body member resides in the patient ear and the therapeutic substance is administered to the patient via the body member.

As set forth above, Rosenman describes a device and method wherein a drug delivery structure is implanted within the myocardium so that the entire structure is at depth below the endocardial surface. As such, Rosenman at least fails to teach or suggest a method of inserting a device into the ear through an incision until the cap member abuts the outside of the incision. Rosenwald describes an implant that is devoid of a cap member of any type and which is inserted inside of a body conduit or orifice and, as such, is never inserted through an incision.

Therefore, even if Rosenman and Rosenwald were combined, the present invention would not be obtained. Accordingly, claim 103 is patentable over Rosenman and Rosenwald. Claims 104 and 106-114 depend from claim 103 and, thus, also are patentable over Rosenman and Rosenwald.

***Altman, Rosenwald, Dinius, and Theeuwes***

Claims 82-89, 91, and 103-114 are rejected under 35 U.S.C. §103(b) under U.S. Patent No. 5,551,427 to Altman (hereinafter “Altman”), Rosenwald, U.S. Patent No. 4,451,254 to Dinius et al. (hereinafter “Dinius”), and U.S. Patent No. 4,014,334 to Theeuwes et al. (hereinafter “Theeuwes”). Applicants respectfully traverse.

Altman describes an implant that is inserted in the myocardium for the treatment of cardiac arrhythmias. Altman’s implant includes a helix 46 that is connected to a head 54 via a linear extension having a distance 56 (see e.g. Fig. 7). Altman’s implant is not inserted into the ear. Further, as shown in Fig. 11, Altman’s implant is not inserted through an incision until the head 54 abuts the incision.

As set forth above, Rosenwald describes a medication delivery vehicle that is inserted within bodily conduits, orifices, vessels and the like (see col. 3, line 48 -line 64). Rosenwald is not inserted through an incision. Further, Rosenwald does not teach or suggest a cap member of any type that abuts an incision through which the device is inserted and which remains outside the incision for stabilizing the device once it is implanted.

Dinius describes an implant and an implanter system for inserting the implant into an animal. The implanter has a sharpened hollow tube that is inserted into and embedded in the animal's body and a plunger that moves implants through the sharpened hollow tube into the animal. The implants 50 are long and cylindrical in shape (see col. 5, lines 41-42; Figs. 1 and 2).

However, like Altman, Dinius does not teach or suggest a method wherein the implant is inserted through an incision until a cap element abuts the incision. Like Rosenwald, Dinius's implant is devoid of a cap element of any kind.

Theeuwes describes an osmotic device that is applied to the surface of the skin (e.g. see Fig. 2, col. 5, lines 23-52), within a body cavity (e.g. see Fig. 3, col. 5, lines 53-64), or under the eyelid in the cul-de-sac (e.g. see Fig. 4, col. 5, line 65 - col. 6, line 38). Theeuwes does not teach or suggest a method of inserting an implant through an incision or in the ear and, further, does not teach or suggest a method wherein the implant is inserted through an incision until a cap element abuts the incision. Like Rosenwald and Dinius, Theeuwes' implant is devoid of a cap element of any kind.

Therefore, even if Altman, Rosenwald, Dinius, and Theeuwes were combined, the present invention would not be obtained. Accordingly, claims 82, 103, and all claims dependent therefrom, are patentable over Altman, Rosenwald, Dinius, and Theeuwes.

***Rosenman and Johnson***

Claim 90 is rejected under 35 U.S.C. §103(a) over Rosenman and U.S. Patent No. 5,972,027 to Johnson (hereinafter “Johnson”).

As set forth above, Rosenman describes a device and method wherein a drug delivery structure is implanted within the myocardium so that the entire structure is at depth below the endocardial surface. As such, Rosenman at least fails to teach or suggest a method of inserting a device into the ear through an incision until the cap member abuts the outside of the incision.

Johnson describes a porous stent for maintaining the patency of body passages (see e.g. col. 1, lines 4-16). Such stents are placed intraluminally within a body passage such as a blood vessel, gastrointestinal tract, ureteral tracts, bronchial and esophageal tracts. Johnson does not teach or suggest a method of inserting an implant through an incision or in the ear and, further, does not teach or suggest a method wherein the implant is inserted through an incision until a cap element abuts the incision. Rather, Johnson’s stent is devoid of a cap element of any kind.

Therefore, even if Rosenman and Johnson were combined, the present invention would not be obtained. Accordingly, claims 82, 103, and all claims dependent therefrom, are patentable over Rosenman and Johnson.

***Altman, Rosenwald, Dinius, Theeuwes, and Johnson***

Claim 90 is rejected under 35 U.S.C. §103(a) over Altman, Rosenwald, Dinius, Theeuwes, and Johnson. Applicants respectfully traverse.

As set forth above, Altman does not teach or suggest a method of inserting an implant into the ear or a method wherein an implant is inserted through an incision until the head 54 abuts the incision.

As further set forth above, Rosenwald's vehicle is not inserted through an incision. Further, Rosenwald does not teach or suggest a cap member of any type that abuts an incision through which the device is inserted and which remains outside the incision for stabilizing the device once it is implanted.

As further set forth above, Dinius does not teach or suggest a method wherein an implant is inserted through an incision until a cap element abuts the incision. Rather, Dinius's implant is devoid of a cap element of any kind.

As further set forth above, Theeuwes does not teach or suggest a method of inserting an implant through an incision or in the ear and, further, does not teach or suggest a method wherein the implant is inserted through an incision until a cap element abuts the incision. Rather, Theeuwes' implant is devoid of a cap element of any kind.

As further set forth above, Johnson n does not teach or suggest a method of inserting an implant through an incision or in the ear and, further, does not teach or suggest a method wherein the implant is inserted through an incision until a cap element abuts the incision. Rather, Johnson's stent is devoid of a cap element of any kind.

Therefore, even if Altman, Rosenwald, Dinius, Theeuwes, and Johnson were combined, the present invention would not be obtained. Accordingly, claims 82, 103, and all claims dependent therefrom, are patentable over Altman, Rosenwald, Dinius, Theeuwes, and Johnson.

## 2. Double Patenting

Claims 82-91 and 103-114 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting over claims 83-110 and 117-120 of copending U.S. Patent Application No. 10/740,698. A terminal disclaimer with respect to U.S. Patent Application No. 10/740,698 is filed herewith. Reconsideration and withdrawal of the rejection is respectfully requested.

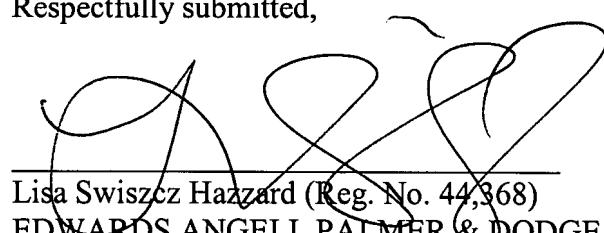
### CONCLUSION

In view of the foregoing, applicants request reconsideration and allowance of claims 82-91 and 103-114.

It is believed that no fees are required for consideration of this response. However, if for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Office is hereby authorized and requested to charge Deposit Account No. **04-1105**.

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Respectfully submitted,



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